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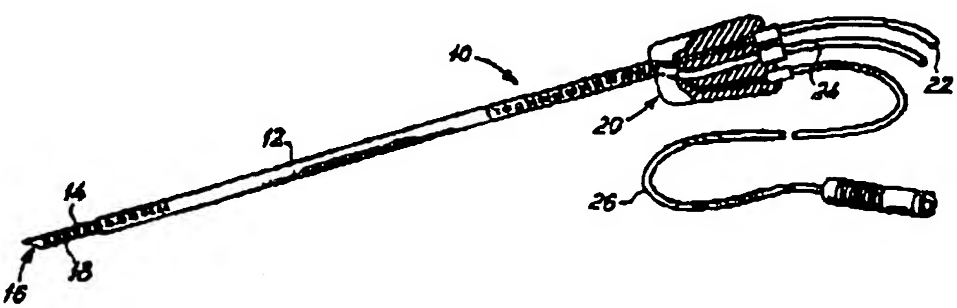
(54) Title: AN ELECTROSURGICAL INSTRUMENT FOR TISSUE ABLATION, AN APPARATUS, AND A METHOD FOR PROVIDING A LESION IN DAMAGED AND DISEASED TISSUE FROM A MAMMAL



(57) Abstract

The invention relates to an electrosurgical instrument, an apparatus and a method for tissue ablation. The invention is useful for performing lesions to tissue, hereby tumours, birth marks, or the like, may be removed. The electrosurgical instrument comprises an elongated tubular element having a distal end and a proximal end, a cooling fluid passage within the tubular element establishes fluid communication between the proximal end and the distal end and an electric conductor, provided at the proximal end, supplies electric energy to the distal end. The apparatus comprises said electrosurgical instrument, means to supply the cooling fluid, a counter electrode and an electric energy source. The method comprises the steps of: 1) to insert the tubular element into tissue, 2) to supply cooling fluid to the tubular element, 3) to supply electric energy to the tubular element.

An electrosurgical instrument for tissue ablation, an apparatus, and a method for providing a lesion in damaged and diseased tissue from a mammal.

The present invention concerns a novel electrosurgical instrument for tissue ablation, an apparatus for tissue ablation comprising the electrosurgical instrument and a method for providing a lesion in damaged or diseased tissue from a mammal. The present invention is useful for providing a lesion in any biological tissue such as tissue from a mammal. Hereby damaged or diseased tissue such as tumors, birth marks, lipomas, or the like, may be removed.

Radiofrequency (RF) tissue ablation is a well known technique for making thermal lesions around the tip of an electrode due to tissue coagulation caused by resistive heating. The electrode can be applicated directly on superficial structures, surgically, endoscopically, laparascopically, or via a transcatheter access - the latter has become a well established treatment for many symptomatic cardiac arrhythmias (see Nath S, Haines DE. Biophysics and pathology of catheter energy deliver systems. Progress in Cardiovascular Disease 1995; 37: 185-204). Furthermore, a needle electrode can be inserted interstitially, mainly guided by imaging. Several studies have evaluated needle electrodes and thermal lesions in different organs such as liver (see McGahan JP, Schneider P, Brock JM, Tesluk H. Treatment of liver tumors by percutaneous radiofrequency electrocautery. Seminars in Interventionel Radiology 1993; 10: 143-149; Rossi S, Fornari F, Buscarini L. Percutaneous ultrasound-guided radiofrequency electrocautery for the treatment of small hepatocellular carcinoma. J Intervent Radiol 1993; 8: 97-103; Solbiati L, Ierace T, Goldberg SN, Livraghi T, Gazelle GS, Rizzatto G. Percutaneous US-guided RF tissue ablation of liver metastases: Long-term follow-up. Radiology 1995; 197(P): 199 (abstr); Livraghi T, Goldberg SN, Lazzaroni S, Meloni F, Monti F, Solbiati L. Saline-enhanced RF tissue ablation in the treatment of liver metastases. Radiology 1995; 197(P): 140 (abstr), prostate (see McGahan JP, Griffey SM, Budenz RW, Brock JM. Percutaneous ultrasound-guided radiofrequency electrocautery ablation of prostate tissue in dogs. Acad Radiol 1995; 2: 61-65, Goldwasser B, Ramon J, Engelberg S. Transurethral needle ablation (TUNA) of the prostate using low level radiofrequency energy: An animal experimental study. Eur Urol 1993; 24: 400-405), and lungs (see Goldberg

SN, Gazelle GS, Compton CC, McLoud TC. Radiofrequency tissue ablation in the rabbit lung: Efficacy and complications. Acad Radiol 1995; 2: 776:784). Finally, needle electrodes have been used in neurosurgery for the interruption of pain pathways (see Anzai Y, De Salles AF, Black KL et al: Stereotactic and interventional MRI, in De Salles AF and Goetsch SJ (eds): Stereotactic Surgery and Radiosurgery. Madison, Medical Physics Publishing. 1993: 47-60).

The electrophysiologic and thermodynamic conditions in monopolar RF tissue ablation have been described by Organ (see Organ LW. Electrophysiologic principles of radiofrequency lesion making. Appl Neurophysiol 1976; 39:69-76) and Nath et al (see Nath S, Haines DE. Biophysics and pathology of catheter energy deliver systems. Progress in Cardiovascular Disease 1995; 37: 185-204; Nath S, Dimarco JP, Haines DE. Basic aspects of radiofrequency catheter ablation. J Cardiovasc Electrophysiol 1994; 5: 863-876): An RF lesion is the result of tissue destruction due to resistive heating in the tissue that surrounds the uninsulated part of the electrode. Resistive heating is proportional to the square of the current density, the latter is inversely proportional to the square of the distance from the ablation electrode. Therefore, resistive heating decreases from the ablation electrode with the distance to the fourth power. In other words, significant resistive heating only occurs within a narrow rim (few mm) of tissue in direct contact with the ablation electrode. Deeper tissue heating occurs as a result of passive heat conduction from that rim.

A general problem in RF tissue ablation is limitation in lesion size. An increased generator power (Watt) and/or exposure time results in an increased amount of delivered energy (Joule) around the electrode with a resulting increased lesion size. However, at high temperatures (>100°C) at the electrode-tissue interface the impedance increases significantly because of desiccation followed by charring around the electrode tip. This leads to an abrupt fall in lesion current (and delivered effect) and no further energy is delivered around the electrode, and no further tissue heating occurs. Lesion size will therefore have an upper limit (see Nath S, Haines DE. Biophysics and pathology of catheter energy deliver systems. Progress in Cardiovascular Disease 1995; 37: 185-204; Organ LW. Electrophysiologic principles of radiofrequency lesion making. Appl Neurophysiol 1976; 39:69-76; Nath S, Dimarco JP, Haines DE. Basic aspects of radiofrequency catheter

ablation. J Cardiovasc Electrophysiol 1994; 5: 863-876). Thus, it has been difficult to chieve a sufficient coagulation depth, i.e. a sufficient transverse diameter of the lesion. A maximum transverse diameter in the range of 10-15 mm is typically reported, (see McGahan JP, Schneider P, Brock JM, Tesluk H. Treatment of liver tumors by percutaneous radiofrequency electrocautery. Seminars in Interventionel Radiology 1993; 10: 143-149; Rossi S, Fornari F, Buscarini L. Percutaneous ultrasound-guided radiofrequency electrocautery for the treatment of small hepatocellular carcinoma. J Intervent Radiol 1993; 8: 97-103; McGahan JP, Griffey SM, Budenz RW, Brock JM. Percutaneous ultrasound-guided radiofrequency electrocautery ablation of prostate tissue in dogs. Acad Radiol 1995; 2: 61-65; Goldwasser B, Ramon J, Engelberg S. Transurethral needle ablation (TUNA) of the prostate using low level radiofrequency energy: An animal experimental study. Eur Urol 1993; 24: 400-405; Goldberg SN, Gazelle GS, Dawson SL, Rittman WJ, Mueller PR, Rosenthall DI. Tissue ablation with radiofrequency: Effect of probe size, gauge, duration, and temperature on lesion wolume. Acad Radiol 1995; 2: 399-404). The longitudinal dimension, however, is simply dependent on the length of the uninsulated part of the electrode (see Goldberg SN, Gazelle GS, Dawson SL, Rittman WJ, Mueller PR, Rosenthall DI. Tissue ablation with radiofrequency: Effect of probe size, gauge, duration, and temperature on lesion wolume. Acad Radiol 1995; 2: 399-404).

Different strategies to increase lesion size by avoidance of charring have been studied: Pulsed RF energy delivery (see Nath S, Whayne JG, Haines DE. Does pulsed radiofrequency delivery result in greater tissue heating and lesion size from catheter ablation. PACE 1993; 16: 947); monitoring and controling the power (see Wittkamp FHM, Hauer RNW, de Medina EOR. Control of radiofrequency lesion size by power regulation. Circulation 1989; 80: 962-968), impedance (see Strickberger SA, Hummel JD, Vorperian VR, et al. A randomized comparison of impedance and temperature monitoring during accesory pathway ablation. Circulation 1993; 88:I-295 (abstr)), and temperature (see Langberg JJ, Calkins H, El-Atassi R, et al. Temperature monitoring during radiofrequency catheter ablation of accessory pathways. Circulation 1992; 86: 1469-1474; Sanchez R, vanSonnenberg E, Agostino HD, Goodacre B, Esch D. Percutaneous tissue ablation by radiofrequency thermal energy as a prelim to tumour ablation. Minimally Invasive Therapy 1993; 2: 299-305);

needle electrodes with either a large radius (see Haines DE, Watson DD, Verow AF. Electrode radius predicts lesion during radiofrequency energy heating. Validation of a proposed thermodynamic model. Circ Res 1990; 67: 124-129), or made by precious metals (see Sanchez R, vanSonnenberg E, Agostino HD, Goodacre B, Esch O. Percutaneous tissue ablation by radiofrequency thermal energy as a prelim to tumour ablation. Minimally Invasive Therapy 1993; 2: 299-305); multi needle electrode application (see Goldberg SN, Gazelle GS, Dawson SL, Rittman WJ, Mueller PR, Rosenthall DI. Tissue ablation with radiofrequency using multiprobe arrays. Acad Radiol 1995; 2: 670-674); porous RF needle electrodes for saline tissue irrigation (see Goldberg SN, Gazelle GS, Solbiati L, Monti F, Livraghi T, Rittman WJ. Saline-enhanced RF tissue ablation: Demonstration of efficacy and optimization of parameters. Radiology 1995; 197(P): 140 (abstr)); and expansible electrodes (see Reidenbach HD. First experimental results with special applicators for high-frequency interstitial thermotherapy. Minimally Invasive Therapy 1995; 4 (Suppl 1): 40 (abstr)). The background prior art has furthermore been disclosed in International Applications WO 95/05212; WO 94/10924; WO 94/11059; US Patent Nos. 5,342,357; 5,348,554; 5,334,193; 5,122,137; 5,383,876; 4,532,924; EP Patent Application Nos. 246,350; 480,639; 274,118; 105,677; 368,161, 608,609; Danish Patent No. 169,644; and DE Offenlegungsschrift 2,407,559. Reference is made to the above Patents and Patent applications, of which the US Patents are hereby incorporated by reference.

An object of the present invention is to provide an electrosurgical instrument which avoids the disadvantages of the prior art electrosurgical instruments.

Another object of the present invention is to prevent charring around the distal end of an electrosurgical instrument.

A further object of the present invention is to provide a lesion of any specific size.

A still further object of the present invention is to provide an apparatus for tissue ablation.

A further object of the present invention is to provide a method for treating damaged or diseased tissue from a mammal.

An even further object of the present invention is to provide larger lesion than hitherto reported.

In a first aspect, the present invention provides an electro-

surgical instrument for tissue ablation, comprising:

i) an elongated tubular element defining a distal end and a promixal end, the distal end being configurated so as to allow the distal end to perforate and penetrate into tissue, and the distal end being exposed for establishing electric and thermal communication to the tissue,

ii) a cooling fluid passage housed within the elongated tubular element and establishing fluid communication from a cooling fluid input provided at the promixal end of the elongated tubular element to the distal end for establishing heat conductive communication therewith and from the distal end to a cooling fluid output provided at the proximal end of the elongated tubular element, and

iii) an electric conductor means provided at the proximal end of the elongated tubular element and establishing electric conductive communication with the distal end for the supply of electric energy to the distal end so as to establish the tissue ablation through the supply of electric energy to the tissue from the distal end and so as to prevent charring of the tissue through cooling the distal end of the tubular elongated element by the supply of cooling fluid to the distal end through the cooling fluid passage.

In the present context, the expression "communication" is to be construed a genetic term comprising the technique of establishing communication for the transfer of electric energy between any two component or elements, and the expression is to be construed comprising conventional expression such as contact, connection, etc., conventionally used in the context of transferring electric energy and/or heat.

In the present context, the term "AC" means alternating current, the term "DC" means direct current, and the term "RF" means radiofrequency, i.e. alternating currents of a frequency useful for radiotransmission such as a frequency between 10 kHz and 100.000 MHz or even higher.

In a first embodiment of the electrosurgical instrument according to the first aspect of to the invention, the cooling fluid passage comprises an inner tube extending co-axially with and essentially in the entire length of the elongated tubular element, wherein the inner tube has an open end portion at the distal end communicating with the distal end of the elongated tubular element, and an opposite open end portion

CLAIMS:

1. An electrosurgical instrument for tissue ablation, comprising:

i) an elongated tubular element defining a distal end and a promixal end, said distal end being configurated so as to allow said distal end to perforate and penetrate into tissue, and said distal end being exposed for establishing electric and thermal communication to said tissue,

ii) a cooling fluid passage housed within said elongated tubular element and establishing fluid communication from a cooling fluid input provided at said promixal end of said elongated tubular element to said distal end for establishing heat conductive communication therewith and from said distal end to a cooling fluid output provided at said proximal end of said elongated tubular element, and

iii) an electric conductor means provided at said proximal end of said elongated tubular element and establishing electric conductive communication with said distal end for the supply of electric energy to said distal end so as to establish said tissue ablation through the supply of electric energy to said tissue from said distal end and so as to prevent charring of said tissue through cooling said distal end of said tubular elongated element by the supply of cooling fluid to said distal end through said cooling fluid passage.

2. The electrosurgical instrument according to claim 1, wherein said cooling fluid passage comprises an inner tube extending co-axially with and essentially in the entire length of said elongated tubular element, wherein said inner tube has an open end portion at said distal end communicating with said distal end of said elongated tubular element, and an opposite open end portion at said proximal end communicating with said cooling fluid output.

3. The electrosurgical instrument according to claim 1, wherein said cooling fluid passage comprises an inner tube extending co-axially with and essentially in the entire length of said elongated tubular element, wherein said inner tube has an open end portion at said distal end communicating with said distal end of said elongated tubular element, and an opposite open end portion at said proximal end communicating with said cooling fluid input.

4. The electrosurgical instrument according to claim 3, wherein said inner tube has an end portion at said distal end provided with a number of holes for supplying said cooling fluid to said distal end of said elongated tubular element.

5. The electrosurgical instrument according to claim 3, wherein said inner tube has a helical structure at said distal end of said elongated tubular element.

6. The electrosurgical instrument according to claims 3 or 4, wherein said inner tube is made of a flexible material.

7. The electrosurgical instrument according to claim 1, wherein said tubular elongated element comprises an inner partition wall extending essentially in the entire length of said elongated tubular element and defining an input and an output part of said cooling fluid passage.

8. The electrosurgical instrument according to any of claims 1 to 7, wherein said elongated tubular element is provided with an insulating material, said insulating material surrounding said elongated tubular element and extending along said elongated tubular element from said proximal end to said distal end so as to provide an exposed distal end.

9. The electrosurgical instrument according to claim 8, wherein said insulating material levels with said exposed distal end of said elongated tubular element.

10. The electrosurgical instrument according to claims 8 or 9, wherein said exposed distal end of said electrosurgical instrument has a length in the range of 1 mm to 1000 mm, e.g. 1 mm to 5 mm, 1 mm to 10 mm, 1 mm to 20 mm, 1 mm to 30 mm, 1 mm to 40 mm, 1 mm to 50 mm, 1 mm to 100 mm, 1 mm to 200 mm, 1 mm to 300 mm, 1 mm to 400 mm, 1 mm to 500 mm, 1 mm to 600 mm, 1 mm to 700 mm, 1 mm to 800 mm, 1 mm to 900 mm, 1 mm to 1000, such as 1 mm to 5 mm, 5 mm to 10 mm, 10 mm to 20 mm, 20 mm to 30 mm, 30 mm to 40 mm, 40 mm to 50 mm, 50 mm to 100 mm, 100 mm to 200 mm, 200 mm to 300 mm, 300 mm to 400 mm, 400 mm to 500 mm, 500 mm to 600 mm, 600 mm to 700 mm, 700 mm to 800 mm, 800 mm to 900 mm,

and 900 nm to 1000 nm.

11. The electrosurgical instrument according to any of claims 1 to 10, wherein said distal end of said electrosurgical instrument has a transversal diameter i the range of 0,1 mm to 5 mm, e.g. 0,1 mm to 0,4 mm, 0,1 mm to 0,6 mm, 0,1 mm to 0,8 mm, 0,1 mm to 1,0 mm, 0,1 mm to 1,2 mm, 0,1 mm to 1,4 mm, 0,1 mm to 1,6 mm, 0,1 mm to 1,8 mm, 0,1 mm to 2,0 mm, 0,1 mm to 3,0 mm, 0,1 to 4,0 mm, 0,1 mm to 5,0 mm, such as 0,1 mm to 0,4 mm, 0,4 mm to 0,6 mm, 0,6 mm to 0,8 mm, 0,8 mm to 1,0 mm, 1,0 mm to 1,2 mm, 1,2 mm to 1,4 mm, 1,4 mm to 1,6 mm, 1,6 mm to 1,8 mm, 1,8 mm to 2,0 mm, 2,0 mm to 3,0 mm, 3,0 mm to 4,0 mm, and 4,0 mm to 5,0 mm.

12. The electrosurgical instrument according to any of claims 1 to 11, wherein said cooling fluid is selected from liquid material and gaseous material and mixtures thereof, said fluid serving to limit the heat transfer from said elongated tubular element to adjacent tissue to an extend sufficient to prevent charring around said distal end of said elongated tubular element.

13. The electrosurgical instrument according to claim 12, wherein said cooling fluid is biologically acceptable and/or compatible with tissue from a mammal and is selected from water, saline, air, nitrogen or the like and mixtures thereof.

14. An apparatus for tissue ablation comprising:

an electrosurgical instrument for tissue ablation, said instrument comprising:

i) an elongated tubular element defining a distal end and a promixal end, said distal end being configurated so as to allow said distal end to perforate and penetrate into tissue, and said distal end being exposed for establishing electric and thermal communication to said tissue,

ii) a cooling fluid passage housed within said elongated tubular element and establishing fluid communication from a cooling fluid input provided at said promixal end of said elongated tubular element to said distal end for establishing heat conductive communication therewith and from said distal end to a cooling fluid output provided at said proximal end of said elongated tubular element, and

iii) an electric conductor means provided at said proximal end of said elongated tubular element and establishing electric conductive communication with said distal end for the supply of electric energy to said distal end so as to establish said tissue ablation through the supply of electric energy to said tissue from said distal end and so as to prevent charring of said tissue through cooling said distal end of said tubular elongated element by the supply of cooling fluid to said distal end through said cooling fluid passage,

means for supplying said cooling fluid to said cooling fluid input of said elongated tubular element,

a counter electrode means, and

an electric energy source for establishing and electric circuitry through said electrosurgical instrument, said tissue and said counter electrode means and for supplying said electric energy to said distal end.

15. The apparatus according to claim 14, said electrosurgical instrument having any of the features of said electrosurgical instrument according to any of claims 2 to 13.

16. The apparatus according to any of claims 14 or 15, said counter electrode means being constituted by a further electrosurgical instrument according to any of claims 1 to 13, and said apparatus constituting a bipolar electrosurgical apparatus.

17. A method for providing a lesion in damaged or diseased tissue from a mammal, comprising:

providing an electrosurgical instrument for tissue ablation, said instrument comprising:

i) an elongated tubular element defining a distal end and a pronixal end, said distal end being configurated so as to allow said distal end to perforate and penetrate into tissue, and said distal end being exposed for establishing electric and thermal communication to said tissue,

ii) a cooling fluid passage housed within said elongated tubular element and establishing fluid communication from a cooling fluid input provided at said promixal end of said elongated tubular element to said distal end for establishing heat conductive communication therewith and

from said distal end to a cooling fluid output provided at said proximal end of said elongated tubular element, and

iii) an electric conductor means provided at said proximal end of said elongated tubular element and establishing electric conductive communication with said distal end for the supply of electric energy to said distal end,

perforating said tissue by means of said elongated tubular element and penetrating said elongated tubular element into said tissue,

providing a means for supplying said cooling fluid and connecting said cooling fluid supplying means to said input provided at said proximal end of said elongated tubular element of said electrosurgical instrument,

providing a counter electrode means and connecting said counter electrode means to said mammal for establishing electric communication therewith,

providing an electric energy source for generating said electric energy and connecting said electric energy source to said electric conductor means of said electrosurgical instrument and to said counter electrode means, and

supplying electric energy from said electric energy source to said distal end of said elongated tubular element of said electrosurgical instrument for establishing said tissue ablation and at the same time supplying said cooling fluid to said distal end of said elongated tubular element of said electrosurgical instrument for preventing charring of said tissue for cooling said distal end, thereby providing a lesion of a specific volume within said tissue.

18. The method according to claim 17, said electrosurgical instrument having any of said features of said electrosurgical instrument according to any of claims 2 to 13, and/or said electrosurgical instrument constituting said electrosurgical instrument of said apparatus according to any of claims 14 to 16.

19. The method according to any of claims 17 or 18, wherein said damaged or diseased tissue comprises a tumor.

20. The method according to any of claims 17 to 19, wherein said electric energy source constitutes a timer controlled constant power RF generator generating a power output of 10-20 W, 20-30 W, 30-40 W, 40-50 W, 50-60 W, 60-70 W of a frequency of 10-20 kHz, 20-40 kHz, 40-80 kHz, 80-160 kHz, 160-320 kHz, 320-640 kHz, 640-1280 kHz, 1280-2560, 2560-5120 kHz, 5120 kHz-10 MHz, 10-20 MHz, 20-40 MHz, 40-80 MHz, 80-160 MHz, 160-320 MHz, 320-640 MHz, 640-1280 MHz, 1280-2560 MHz, 2560-5120 MHz, 5120-10.000 MHz, 10.000-20.000 MHz, 20.000-40.000 MHz, 40.000-80.000 MHz, 80.000-100.000 MHz.